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IN THE

Supreme Court of the United States

DANIEL CHAPTER ONE, ET AL.,
Petitioners,
v.
FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

BRIEF *AMICUS CURIAE* OF FOUNDATION FOR HEALTH CHOICE AND CITIZENS FOR HEALTH IN SUPPORT OF PETITIONERS

JAMES S. TURNER*
BETSY E. LEHRFELD
SWANKIN & TURNER
1400 16TH STREET, NW
WASHINGTON, DC 20036
(202) 462-8800
jim@swankin-turner.com
Attorneys for Amici Curiae

**Counsel Of Record*
May 13, 2011

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INTEREST OF *AMICI CURIAE*[1]

The *Amici* herein are the Foundation for Health Choice, an organization of health care practitioners and consumers, and Citizens for Health, a natural health consumers' organization. Between them, these organizations have decades of involvement representing consumer rights in the health policy arena and represent tens of thousands of their members as well as the general public. Their interest is in protecting the rights of consumers to health choice and access to health information. They enter this case as *amici* in order to advance these important rights which they believe and assert are endangered unconstitutionally by the decision of the Federal Trade Commission (FTC) in this case. Without protection for these rights, not only will current consumers be denied self-determination in one of the most personal and private areas of life, but the development of new approaches to health care for the future will be stunted by the sacrifice of diversity to orthodoxy.

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[1] The parties were given timely notice of and have consented to the filing of this brief in letters of consent on file with the Clerk. No counsel for any party had any role in authoring this brief, and no one other than the *Amici Curiae* provided any monetary contribution to its preparation or submission. Counsel for *Amici* represented Petitioners in the administrative hearing phase of these proceedings but other counsel have represented Petitioners in all judicial phases of these proceedings over the past seventeen months.

SUMMARY OF ARGUMENT

The court should grant certiorari for the following reasons:

The issues presented in this case relate to a core legal principle that impacts large numbers of consumers, beyond the followers of Petitioner. The health maintenance concerns at the heart of this case are exactly the kind of concern that this court had in mind when it said, "...the particular consumer's interest in the free flow of commercial information, ...may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). The FTC's position, that only double blind, placebo controlled studies can constitute the "competent and reliable scientific evidence" required by the FTC statutory standard, is legislatively incorrect and Constitutionally impermissible. Petitioners provided expert testimony that their statements were supported by "competent and reliable scientific evidence." The FTC's response, adopted by the FTC Administrative Law Judge and by the Federal Trade Commission itself, was to enshrine the testimony of their single expert, that double blind, placebo controlled studies were the only applicable standard, as the law in this case. This decision deprives millions of consumers who are making decisions every day relying on the type of evidence presented by Petitioners' experts, of the right to make those decisions. The Constitution does

not permit the government to suppress consumer access to such information. Consumers have a Constitutionally protected basic human right, beyond the religious right of Petitioner's followers, to the information that Petitioners' experts, who the FTC accepted as experts, testified was supported by "competent and reliable scientific evidence" other than double blind, placebo controlled studies. In addition, Federal courts are increasingly being called upon to decide questions about FTC regulation of health claims for herbal and nutritional products such as those at issue in this case and guidance for them will help reduce social tension around food regulation.

This court should grant certiorari so that these issues, which are currently at the core of a national public debate about when and how less intrusive herbal and dietary remedies can be integrated into the conventional drug, radiation and surgery-based health care approaches, can be fully and finally made clear to consumers, producers, and regulators of health claims for foods and to the courts being asked to decide such controversies.

ARGUMENT

I. THIS COURT HAS HELD THAT COMMERCIAL SPEECH IS CONSTITUTIONALLY PROTECTED AND HEALTH CLAIMS FOR PRODUCTS CONSTITUTE COMMERCIAL

SPEECH AND ARE MATTERS OF OPINION RATHER THAN MATTERS OF FACT.

A. A Statement That A Substance Cures A Condition Is A Matter Of Opinion, Rather Than A Matter Of Fact.

In *United States v. Johnson*, 221 U.S. 488 (1911), Justices Oliver Wendell Holmes, for the majority, and Charles Evans Hughes, in dissent, set out a clear way to think about, and resolve, the issues presented in the present case. By reviewing their reasoning, this court can resolve a raging national controversy[2] over the role of claims about

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[2] Appeals courts are approaching this issue in varying ways, for example:

The U.S. Court of Appeals for the Tenth Circuit, in *Nutraceutical Corporation; Solaray, Inc., Plaintiffs-Appellees, v. Andrew Von Eschenbach, Acting Commissioner, U.S. Food and Drug Administration*, 459 F.3d 1033, August 17, 2006, reversed the lower court denial of the regulator's authority defining for the first time the standard of review that Congress intended for courts to use in reviewing actions of the federal agencies, finding that when Congress used the word *de novo* in the Dietary Supplement and Health Education Act of 1994 it did not intend to apply it to court review of agency actions.

Compare to:

The U.S. Court of Appeals for the Third Circuit, in *Federal Trade Commission, Appellant, v. Lane Labs-USA, Inc; Cartilage Consultants, Inc.; I. William Lane; Andrew J. Lane*, App No. 09-3909, 2010 WL 4226509 (3d Cir. Oct. 26, 2010),

reversed a lower court denial of regulatory authority but remanded the case for factual determination as to whether Lane Labs' alleged violations of a previous consent order were technical or inadvertent, allowing a substantial compliance defense if they were inadvertent.

The implication of the issue playing out in various courts is set forth in "Has the FTC Changed the Game On Advertising Substantiation?" by Randal Shaheen and Amy Ralph Mudge, *Antitrust*, Vol. 25, No. 1, Fall 2010 © 2010 by the American Bar Association. They say, citing David C. Vladeck, Director, Bureau of Consumer Protection, Fed. Trade Comm'n, Remarks Before the Council for Responsible Nutrition's Annual Symposium for the Dietary Supplement Industry, Priorities for Dietary Supplement Advertising Enforcement (Oct. 22, 2009), *http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf*,

> Since its loss in *Lane Labs*, FTC staff has stated that it intended to modify its traditional requirement of competent and reliable scientific evidence."23The Director of the Bureau of Consumer Protection, David Vladeck (a seasoned public interest litigation lawyer), has also stated that he would seek more precise order language as to the amount and type of scientific evidence necessary to support health claims, as well as pursue efforts to harmonize FTC with FDA requirements. He indicated that an "outlier study," even if well conducted, should not be sufficient basis for a health claim.

To protect against one "outlier" study in the enforcement of a consent order the FTC has enthroned the double blind placebo controlled study as the sole support for its enforcement actions.

complementary and alternative approaches to health, such as the use of herbs and nutrients, as defined by the National Institutes of Health's National Center for Complementary and Alternative Medicine (NCCAM), and provide a Constitutional context to guide future action by producers, sellers, regulators, consumers and courts.

The *Johnson* case addressed the fact that Mr. Johnson shipped a drug from Missouri to Washington, DC, claiming on the label that it would cure cancer when he knew it would not cure cancer. *Johnson*, p. 488. The lower court held that the Pure Food and Drug Act of 1906 did not make such statements illegal. This court affirmed the lower court decision, with Justice Hughes, joined by Justice Harlan and Justice Day, dissenting.

Justice Holmes, writing for the court majority, said, "It is a postulate, as the case comes before us, that in a certain sense the statement on the label was false, or, at least, misleading. What we have to decide is whether such misleading statements are aimed at and hit by the words of the act. It seems to us that the words used convey to an ear trained to the usages of English speech a different aim; and although the meaning of a sentence is to be felt rather than to be proved, generally, here, the impression may be strengthened by argument, as we shall try to show." *Johnson*, p. 488.

Justice Holmes's argument concluded that Congress intended the Pure Food and Drug Act of 1906 to restrict false or misleading claims about the

content, ingredients, origin, etc., of a product, "matters of fact" he called them, and did not intend to restrict claims about what a product might do, which he considered "matters of opinion." Congress, he said, "was much more likely to regulate commerce in food and drugs with reference to plain matters of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart. See *American School v. McAnnulty*, 187 U. S. 94, 47 L. ed. 90, 23 Sup. Ct. Rep. 33." *Johnson*, p. 488.

Justice Hughes, writing the dissent, said, "The question, then, is whether, if an article is shipped in interstate commerce, bearing on its label a representation that it is a cure for a given disease, when, on a showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat, the act of Congress can be said to apply to it. To my mind the answer appears clear." *Johnson*, p. 489. To Justice Hughes the clear answer was "yes," the statutes applied. In a case where the authorities proved by a "showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat" the statue applied.

The *Johnson* case addresses the question of how the law, as applied by regulators, should deal with differences of opinion that cannot easily be settled by facts. While they disagreed over the application of the 1906 Act in the Johnson case, Holmes and

Hughes agreed that in order to act the authorities need to rely on fact, not opinion. Thus Justice Hughes argued that, in a case where it was established as a matter of fact that a claim for a product was "absolutely worthless and an out-and-out cheat," Congress could act against it. The matter that these two giants of the law struggled over in *Johnson* was addressed in a 1974 FTC proceeding that proposed banning the word "organic," from all commerce. The FTC ALJ rejected the FTC proposal saying "to ban the word 'organic',,,[is] a legal, if not a linguistic error..."[3]

The *Johnson* case did not reach the constitutional question, because the majority disposed of it as a legislative interpretation case because Congress's intent could be interpreted as dealing purely with facts. Petitioners in this case now clearly put before the court the question of how far regulators can go in banning commercial words and statements that current medical/health orthodoxy, represented by double blind, placebo controlled studies, finds offensive to its views. In this case Petitioners

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[3] Proposed Trade Regulation Rule: Food Advertising [16 CFR Part 437] Report of the Presiding Officer Public Record Number 215-40, p. 239, February 21, 1978. If the FTC had been successful in banning the word "organic" from commerce it is unlikely that the current multibillion dollar organic food business, supported by millions of American consumers, would have come into existence.

presented expert witnesses who testified that the statements made by Petitioners were supported by "competent and reliable scientific evidence." The FTC rejected this testimony and banned the statements. The court needs to review this debate to clarify the terms on which the Constitution allows it to be conducted.

II. THE FIRST AMENDMENT PROTECTS THE EXPRESSION OF OPINION

A. Robust Commercial Speech Is An Important National Asset

In *FTC v. QT*, 512 F.3d 858 (7th Cir., 2008) the U. S. Court of Appeals for the Seventh Circuit spelled out the argument being placed before this court by Petitioners.

> Defendants maintain that the magistrate judge subjected their statements to an excessively rigorous standard of proof. Some passages in the opinion could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study: that is, a study in which some persons are given the product whose effects are being investigated while others are given a placebo (with the allocation made at random), and neither the person who

> distributes the product nor the person who measures the effects knows which received the real product. Such studies are expensive, not only because of the need for placebos and keeping the experimenters in the dark, but also because they require large numbers of participants to achieve statistically significant results. Defendants observe that requiring vendors to bear such heavy costs may keep useful products off the market (this has been a problem for drugs that are subject to the FDA's testing protocols) and prevent vendors from making truthful statements that will help consumers locate products that will do them good.
>
> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false.

Petitioners ask and *Amici* here support their request that this court resolve the question of the degree to which the First Amendment protects commercial speech that makes health claims based on evidence other than double blind, placebo

controlled clinical trials. The FTC is insistent on asserting that a double blind, placebo controlled study is the only kind of study that can provide "competent and reliable scientific evidence" that a commercial speech statement is not false or misleading. Petitioners ask this court to resolve this issue, and contend that the FTC ruling violates this court's interpretation of the protections provided to commercial speech by the Constitution. Petitioners urge the court to make the position of the Seventh Circuit in *FTC v. QT* its holding in this case.

In another case, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), strikingly similar to this case and involving comparable marketing claims for dietary supplements, the U.S. Court of Appeals for the District of Columbia rejected the position taken by the FTC in this case. The *Pearson* court applied the First Amendment commercial speech doctrine to claims that did not meet an FDA "scientific" standard—"significant scientific agreement"—similar to the standard relied on by the FTC in this case.

In *Pearson*, as here, marketers of dietary supplements made health claims not supported by double blind, placebo controlled studies. *Compare Pearson*, 164 F.3d at 652 *with* FTC Initial Decision, pp. 83-95. In *Pearson*, as here, the government agencies found these claims misleading because they did not meet the agencies' "scientific" standards. *Compare Pearson*, 164 F.3d at 652-55 *with* FTC Initial Decision, pp. 99-106. Thus, in *Pearson*, as here, the government agencies asserted that the

health claims were "entirely outside the protection of the First Amendment." *Compare Pearson*, 164 F.3d at 655 *with* FTC Initial Decision, pp. 115-16. In *Pearson*, however, the Court of Appeals rejected the agency's claim (calling it "almost frivolous"), whereas in this case, the FTC and the lower court embraced it.

The *Pearson* decision relied on three prior cases applying First Amendment commercial speech doctrine — *In re R.M.J.*, 455 U.S. 191 (1982), *Ibanez*, 512 U.S. 136 (1990), and *Peel v. Attorney Registration and Disciplinary Comm'n. of Illinois*, 496 U.S. 91 (1990). The court in *Pearson* rejected the FDA's contention that health claims, unless consistent with the then-prevailing scientific consensus, were inherently misleading and thus not protected free speech. It found the FDA's argument unpersuasive because it was based upon the unconstitutional "paternalistic assumption" that the ordinary consumer was unable to make an informed and independent judgment on the truthfulness of health claims for vitamins and other dietary supplements. *Pearson*, 164 F.3d at 655.

In this case the FTC dismissed *RMJ*, *Ibanez*, and *Peel*, as "inapposite." FTC Initial Decision, p. 116. In fact, the FTC embraced the "paternalistic assumption" that health claims must meet a "high level of substantiation, such as scientific tests" because it is "difficult or impossible for consumers to evaluate [health claims] for themselves." FTC Initial Decision, p. 102. In so ruling, the FTC violated the "general rule ... that the speaker and the audience,

not the government, assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) [emphasis added]. Indeed, the FTC's paternalistic insistence that Petitioners' claims be measured by current scientific orthodoxy directly contravenes the First Amendment's commitment to "the free flow of commercial information" which, to an individual consumer seeking a solution to a personal health need, "may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976).

The *Pearson* court recognized what the FTC did not — the First Amendment protects the people from government suppression of commercial information if that suppression rests upon a paternalistic policy. Indeed, from the beginning of the development of its First Amendment commercial speech doctrine, the court has consistently rejected paternalistic justifications for suppression of information, knowing "that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to **open** the channels of communication rather than to close them." *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002), quoting from *Virginia State Board of Pharmacy*, 425 U.S. at 769 [emphasis added].

This does not mean that the government may not protect the people from demonstrably fraudulent

advertising. The complaint in this case, however, does not allege that Petitioners' health claims are false; rather, it rests upon the allegation that Petitioners did not have a "reasonable basis" of the sort that the FTC would accept for its health claims: double blind, placebo controlled, clinical trials. FTC Initial Decision, pp. 67, 99. These two standards — falsity in fact and lack of a reasonable basis — are drastically different. The "falsity" theory **requires the government** to "carry the burden of proving that the express or implied message conveyed by the ad is false." FTC Initial Decision, p. 99, n.4. The "reasonable basis theory" **requires the marketer** to demonstrate that it relied upon "competent and reliable scientific evidence," in this instance defined as double-blind, placebo-controlled clinical trials, for its health claims. FTC Initial Decision, p. 100.

The Petitioners argue, and *Amici* support, first, that it is the government's responsibility to show that the Petitioners in this case did not have a "reasonable basis" for their claims. FTC denied that the government has this responsibility and offered no evidence other than asserting that Petitioners lacked double-blind, placebo-controlled, clinical studies. Second, Petitioners argue, supported by their experts, that they did have competent and reliable scientific evidence, recognized in herbal medicine circles around the world, to support their claims.

According to the FTC, since Petitioners did not meet the government's "reasonable basis" standard of double-blind, placebo-controlled, clinical studies,

they are not entitled to the First Amendment protection afforded commercial speech. FTC Initial Decision, pp. 115-16. By so ruling, the FTC erroneously shifted to Petitioners the burden of proving that the First Amendment applied to their health claims and adopted the position that the Constitution permitted the FTC to prohibit Petitioners from making truthful statements about the relationship between their herbal supplements and specific health conditions.

The government has the burden of proof that Petitioners marketing claims are misleading. *Ibanez*, 512 U.S. at 138-39; *Peel*, 496 U.S. at 100-01; *In re RMJ*, 455 U.S. at 202-03. As noted above, the FTC ignored these cases as inapplicable. Relying on all three cases, the *Pearson* court rejected the FDA's effort to shift the burden of proof from the regulators to the marketer of dietary supplements to show that its claims were not "unscientific," and thus, not "inherently misleading." *Pearson*, 164 F.3d at 655. By refusing to apply *Ibanez*, *Peel*, and *In re RMJ*, the FTC and the court that affirmed its decision committed reversible error by failing to apply to Petitioner's health claims the First Amendment test set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980), discussed below.

In a third case, *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002), addressing drug compounding, a process by which a pharmacist or doctor combines, mixes, or alters

ingredients to create a medication tailored to an individual patient's needs, which is at least as, if not more, complex then choosing to use herbal supplements, this court explicitly held that commercial speech receives First Amendment protection, and "explained the reasons for this protection" as follows:

> It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end the free flow of commercial information is indispensable.... Indeed, we recognized that a particular consumer's interest in the free flow of commercial information ... may be as keen, if not keener, by far, than his interest in the day's most urgent political debate. *Thompson*, pp. 366-67.

> Additionally, the court "emphasized":
> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is

entitled to coverage of the First Amendment. *Thompson*, p. 367.

The record shows that Petitioners' statements fall squarely within this court's First Amendment umbrella. The people seeking out Petitioners' information are looking for natural, non intrusive approaches to address their life situations. The information they receive is, according to the experts Petitioners called to testify, supported by "competent and reliable scientific evidence." The FTC, supported by the court below, seeks to block consumer access to this information as unprotected commercial speech.

In recognition of the First Amendment commitment to keep the channels of communication open, this court has imposed strict rules designed to limit government efforts to close them off, insisting that any such regulation must "directly advance" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, p. 367. This case offers the court the opportunity to determine whether requiring double blind, placebo controlled clinical studies to support health claims for herbal supplements unnecessarily burdens the consumer's right to hear and the producer's right to speak. *Amici* urge the court to take this opportunity.

B. The First Amendment Standards Set Out By This Court Support Petitioners' Rights To Protected Speech.

The FTC, supported by the court below, misinterpreted and misapplied the U.S. Supreme court holding in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), concerning the regulation of commercial speech. To understand their error, a review of constitutional analysis arising from *Central Hudson* is in order. *Amici* urge this court to accept the petition seeking review of this case to determine if the Commercial Speech tests set out by this court have been properly applied by the FTC. *Amici* believe they have not for the following reason.

In 1995, this court restated its *Central Hudson* formula, asserting that "the government may freely regulate commercial speech that ... is misleading," but established conditions for doing so *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623-24 (1995). By means of this statement, the court confirmed that the threshold burden for regulating commercial speech is the government's, to show that statements in question are misleading, rather than the semantic shift in burden that results from requiring a commercial statement to be non-misleading. Highlighting this clarification, the court conformed its statement of the *Central Hudson* rule to the several court decisions that it had handed down in the 15 previous years since *Central Hudson* had been decided.

For instance, in 1982, the court, applying *Central Hudson*, ruled that a particular attorney

advertisement could not be "prohibited entirely," there being nothing in the record to show that the ad was either "inherently likely to deceive" or that the ad "has in fact been deceptive." *In the Matter of R. M. J.*, 455 U.S. 191, 202 (1982).

Then, in 1990, the court conferred First Amendment protection on another attorney promotional statement, on grounds that refute the FTC's position in this case. It said:

> (a) "[t]here is no contention that any client or person was actually misled or deceived by Petitioner's stationery;" nor
>
> (b) "any factual finding of actual deception or misunderstanding"; but only
>
> (c) a "conclu[sion], as a matter of law, that Petitioner's claims ... were necessarily misleading."
> *Peel*, 496 U.S. 91 100-01 (1990).

Thus, the *Peel* court concluded that, "[g]iven the complete absence of any evidence of deception in the present case, we must reject the contention that Petitioner's letterhead is actually misleading." *Id.*, 496 U.S. at 106. What the court prohibited in *Peel* is exactly what the FTC is doing in this case.

Four years later, in 1994, this court restated the *Central Hudson* rule and its rationale, as follows:

> Because disclosure of truthful, relevant information is more likely to make a positive contribution to decision making than its concealment of such information, ..., **only false, deceptive, or misleading commercial speech may be banned** .... *Ibanez*, 512 U.S. 136, 142 (1994). [emphasis added]

Thus, the *Ibanez* court ruled in favor of yet another attorney ad where "[t]he record reveals that the Board [of Accountancy] has not shouldered the burden that it must carry in matters of this order:"

> It has **not demonstrated** with sufficient specificity that any member of the public could have been misled by Ibanez' constitutionally protected speech or that any harm could have resulted from allowing that speech to reach the public's eyes. *Ibanez*, 512 U.S. at 138-39 [emphasis added].

Petitioners did not stand idly by in their relationship with the people who used their herbs. Rather they provided information to help their followers make better decisions. Complaint Counsel asserts, but offers no evidence, that since the information provided by Petitioners was not based on double-blind, placebo-controlled clinical studies it was inherently misleading. Nor did FTC cite any evidence that suppressing Petitioners' claims

"directly advances" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 367.

Not only must the government agency that seeks to suppress commercial speech meet its burden to prove the commercial speech at issue to be false, misleading or deceptive, as a matter of fact, but it must also "show that the restriction directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142. Again, as the *Ibanez* court emphasized, "[t]he State's burden is not slight; the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Ibanez.*, 512 U.S. at 143.

In *Edenfield v. Fane*, 507 U.S. 761 (1995), the court explained that the government's "burden is not satisfied by mere speculation or conjecture," but only by "demonstrat[ing] that the harms [the government] recites are real and that restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. This requires actual, extrinsic evidence – not presumption.

Later that same year, in *Rubin v. Coors Brewery Co.*, 514 U.S. 476, 487 (1995), the court further stressed that unless this "critical" requirement is met, "a State could with ease restrict

commercial speech in the service of ... objectives that could not themselves justify a burden on commercial speech." *Edenfield*, 507 U.S. at 771.

In sum, a long line of Supreme court cases has demonstrated the requirement that "the Government bears the burden of **identifying** a substantial interest and **justifying** the challenged restriction." *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 183 (1999) (emphasis added). *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002). *Amici* believe that the FTC is wrong in concluding that it has met this burden and urges the court to accept this petition to finally complete the task of guiding lower courts and regulators on how to address conflicts such as these.

CONCLUSION

Petitioners raise issues about the right to speak and the right to hear unorthodox health information that is supported by "competent and reliable scientific evidence," other than prohibitively costly double blind placebo controlled clinical trials. The area of discourse about such health claims is replete with conflict across the society. *Amici* believe that if this court accepts Petitioners' petition it will be able to effectively bring to a close the national contentious debate about protection of commercial speech that affects herbal and dietary health products.

For the foregoing reasons, *Amici* urge the court to grant the petition.

Respectfully submitted,

JAMES S. TURNER*
BETSY E. LEHRFELD
SWANKIN & TURNER
1400 16TH STREET, NW
WASHINGTON, DC 20036
(202) 462-8800
jim@swankin-turner.com
Attorneys for Amici Curiae

**Counsel Of Record*
May 13, 2011